## REMARKS

This communication is responsive to the Office Action dated August 30, 2010. Claims 1, 3, 44, and 47 are amended, and claims 5 and 42 are cancelled. Claims 1-4, 6, 43-47, and 49-59 are pending. No new matter is added.

## **Examiner Interview**

Applicant's representative Robert E. Ray (USPTO Reg. No. 63,953) thanks Examiner Kai Rajan and the Examiner's supervisor Henry Johnson for the telephonic Examiner Interview initiated by Applicant's representative and conducted November 10, 2010. In the telephonic Interview, the parties discussed the Rule 131 Declarations submitted December 19, 2007. No agreement was reached regarding the allowance of Applicant's claims. No exhibits were introduced.

## Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-6 and 42-59 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,361,522 to Scheiner et al. (hereinafter "Scheiner"). Applicant respectfully traverses the rejection. The Sheiner reference fails to disclose or suggest each and every feature of the invention defined by Applicant's claims, as required by 35 U.S.C. 102(e), and provide no teaching that would have suggested an apparent reason to include such features.

For example, Sheiner fails to disclose or suggest an interactive remote drug dose and physiologic response monitoring system in a patient under a prescriptive regimen to take a drug that includes "a drug delivery device, and an implantable medical device (IMD) in wireless communication with the drug delivery device, the IMD having means for receiving, from the drug delivery device, a communication indicating administration of a drug by the drug delivery device in compliance with a prescriptive regimen, wherein the IMD is configured to modify at least one therapy delivered by the IMD based on the communicating indicating administration of the drug by the drug delivery device, as required by Applicant's independent claim 1, as amended.

As another example, Sheiner fails to disclose or suggest a drug delivery monitoring system that includes "means for monitoring parameters of a drug delivery device, means for communicating the monitored parameters with an implantable medical device (IMD), means for processing the monitored parameters, and means for controlling a therapy delivered by the IMD based upon the monitored parameters of the drug delivery device," as required by Applicant's independent claim 4. as amended.

As another example, Sheiner fails to disclose or suggest an implantable medical device that includes "a controller for controlling cardiac therapy parameters, and one or more electrodes for delivering electrical stimulation to cardiac tissue and monitoring physiologic parameters of the tissue, wherein the controller receives the parameters from the one or more electrodes and information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, wherein the controller varies the cardiac therapy delivery through the one or more electrodes based upon the parameters and the information," as required by Applicant's independent claim 6, as previously presented.

Claims 1 and 4 have been amended herein to recite subject matter of previously presented claims 5 and 42, respectively. The Office Action stated at page 6 that Sheiner discloses the features of previously presented claims 5 and 42 (now cancelled) at column 1, lines 64-67; column 2, lines 1-8 and 51-67; and at column 3, lines 1-50. Regarding the subject matter of previously presented claim 6, the Office Action stated that claim 6 is rejected on the same basis as previously presented claims 1 and 3.

Applicant respectfully disagrees that Sheiner discloses or suggests the features of amended independent claims 1, 4, and 6. Instead, Sheiner merely describes a drug delivery device configured to deliver a transdermal drug in accordance with a signal received from an implantable cardiac device. For example, at column 2, lines 1-8, Sheiner discloses that "[t]he drug delivery device is preferably an electrically modulated transdermal drug delivery device for delivering the drug transdermally in accordance with a signal received from the implantable cardiac device."

As another example, at column 3, lines 26-34, Sheiner discloses "[a] telemetry interface 40 enables the device to communicate with an external programmer via modulated radio frequency waves as well as transmit a command signal to the drug delivery device upon detection of a particular medical condition such as an arrhythmia." In these portions, Sheiner merely describes controlling a transcutaneous (non-implanted) drug delivery device based on a signal received from an implantable cardiac device. Sheiner does not disclose or suggest any

control of an implantable device, such as a therapy delivered by the implantable device, based on information received from a drug delivery device.

As such, Sheiner does not disclose or suggest an IMD that is "is configured to modify at least one therapy delivered by the IMD based on the communicating indicating administration of the drug by the drug delivery device," as recited by Applicant's amended independent claim 1. Sheiner also fails to disclose or suggest a drug delivery monitoring system that includes "means for controlling a therapy delivered by the IMD based upon the monitored parameters of the drug delivery device," as required by Applicant's amended independent claim 3. Sheiner also fails to disclose or suggest a controller that "receives the parameters from the one or more electrodes and information from a drug delivery device, the information identifying whether an expected drug therapy is delivered" and that "varies the cardiac therapy delivery through the one or more electrodes based upon the parameters and the information," as recited by Applicant's independent claim 6 as previously presented.

As set forth above, Sheiner fails to disclose or suggest the features of independent claims 1, 4, and 6. Claims 1, 4, and 6 are therefore in condition for allowance. Dependent claims 2, 3, 43-47, and 49-59 each incorporate all elements of their respective base claims 1, 4, and 6, and are therefore also in condition for allowance. Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-4, 6, 43-47, and 49-59.

## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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